

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2000 list were published in the Federal Register in April 2000.

New Approvals

NADA Number: 141-162

Trade Name:	Zodiac [®] Fleatrol [™] Flea Caps [™] , Hartz [®] Flea Control Capsules [™]
Ingredients:	(S)-Methoprene
Sponsor:	Wellmark International
Approval Date:	January 24, 2000
Status:	Over-the-counter
Route:	Oral
Species:	Dogs
Drug Form:	Capsule
Concentration:	154, 308, or 462 milligrams per capsule
Indications:	For use in dogs, nine weeks of age or older and four pounds body weight or greater, for the prevention and control of flea populations.
Patent Number:	Pending
Exclusivity:	5 years
21CFR 520.1390 and 510.600	

Supplemental Approvals

NADA Number: 141-067

This supplemental application provides for a change of dosage from the original approval of 30 milliliter per kilogram to a flexible dose range of 10 to 30 milliliter per kilogram of body weight.

Trade Name:	Oxyglobin [®] Solution		
Ingredients:	Hemoglobin Glutamer-200 (bovine)		
Sponsor:	Biopure Corporation		
Approval Date:	January 11, 2000		
Status:	Prescription only		
Route:	Intravenous		
Species:	Dogs		
Drug Form:	Solution		
Concentration:	13 grams per deciliter		
Indications:	For the treatment of anemia by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).		
Patent Number:	5,084,558		Expiration Date:
January 28, 2009			
	5,296,465		
	March 22, 2011		
	5,618,919		

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	April 14, 2014		
Exclusivity:	3 years		
21CFR 522.1125			

NADA Number: 097-222

This supplemental application provides for amending the milk discard statement to state the milk discard time only (removes reference to the number of milkings).

Trade Name:	Cefa-Lak [®] , Today Intramammary Infusion
Ingredients:	Cephapirin sodium
Sponsor:	Fort Dodge Animal Health, Division of American Home Products Corp.
Approval Date:	February 4, 2000
21CFR 526.365	

NADA Number: 131-675

This supplemental application provides for establishing tolerances for residues of fenbendazole in edible tissues of swine.

Trade Name:	Safe-Guard [®] Type A Medicated Article
Ingredients:	Fenbendazole
Sponsor:	Hoechst Roussel Vet
Approval Date:	February 10, 2000
Status:	Over-the-counter
Route:	Oral
Species:	Swine
Drug Form:	Type A Medicated Article to make Type B and C medicated feeds.
Concentration:	18.1, 36.2, and 90.7 grams per pound
Indications:	For the removal of: adult stage lungworms (<i>Metastrongylus apri</i> and <i>M. pudendotectus</i>); adult and larvae (L3, 4 stages-liver, lung, intestinal forms) large roundworms (<i>Ascaris suum</i>); adult stage nodular worms (<i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i>); small stomach worms (<i>Hyostrongylus rubidus</i>); adult and larvae (L2, 3, 4 stages-intestinal mucosal forms) whipworms (<i>Trichuris suis</i> ; adult and larvae kidney worms (<i>Stephanurus dentatus</i>).
Tolerance:	21CFR 556.275: The tolerances established for unchanged fenbendazole are 6 parts per million in liver (target tissue) and 2 parts per million in muscle. The Acceptable Daily Intake (ADI) is 40 micrograms per kilogram of body weight per day.
Withdrawal:	Zero days
21CFR 556.275	

New Sponsor

Wellmark International
1000 Tower Road
Suite 245
Bensenville, IL 60106
Drug labeler code : 011536

Change of Sponsor

NADA Number: 113-510

Actions Taken by FDA Center for Veterinary Medicine

From: Merial Ltd.
To: Vétoquinol N.-A., Inc.
2000 Chemin Georges
Lavaltrie (PQ), Canada J0K 1H0
Drug labeler code: 059320

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor Address

International Nutrition, Inc.
7706 'I' Plaza
Omaha, NE 68127
Drug labeler code: 043733

Suitability Petition Action

Number:	00P-1225/CP1
Sponsor:	Equi Aid Products, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, ivermectin, which differs from the pioneer product, ivermectin (Eqvalan), Merial Ltd., NADA 140-439 by the following characteristics: the generic product will consist of a different dosage form (Type A Medicated Article), route of administration (via feed), and strength (5%) from the pioneer.
Action:	Filed on March 31, 2000

Technical Amendment

NADA Number: 141-034

This amendment is to update and improve the accuracy of the regulation. This notice amends the regulation to state the correct use level of 2 to 40 grams of bambermycins per ton of feed.

Trade Name:	Gainpro® Type A Medicated Article
Ingredients:	Bambermycins
Sponsor:	Hoechst Roussel Vet
Effective Date:	April 18, 2000
21CFR 558.95	